

# CytoSorbents™



HELPING REDUCE DEADLY UNCONTROLLED INFLAMMATION IN HOSPITALIZED PATIENTS WORLDWIDE

NASDAQ: CTSO

Biotech Showcase Investor Presentation

January 7, 2019

# Safe Harbor Statement

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This presentation contains “forward-looking statements” pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain the words “estimate,” “intend,” “target,” “will,” “is likely,” “would,” “may,” or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements are found at various places throughout this presentation and include information concerning possible or assumed future results of our operations; business strategies; future cash flows; financing plans; plans and objectives of management; any other statements regarding future operations, future cash needs, business plans and future financial results, and any other statements that are not historical facts. Unless otherwise indicated, the terms “CytoSorbents,” “Company,” “we,” “us” and “our” refer to CytoSorbents Corporation. Any or all of the forward-looking statements included in this presentation are not guarantees of future performance and may turn out to be inaccurate. These forward-looking statements represent our intentions, plans, expectations, assumptions and beliefs about future events and are subject to risks, uncertainties and other factors. Many of those factors are outside of our control and could cause actual results to differ materially from the results expressed or implied by those forward-looking statements. Although these expectations may change, we are under no obligation to inform you if they do. Actual events or results may differ materially from those contained in the forward-looking statements. The following factors, among others, could cause our actual results to differ materially from those described in a forward-looking statement: our history of losses; potential fluctuations in our quarterly and annual results; competition, inability to achieve regulatory approval for our device, technology systems beyond our control and technology-related defects that could affect the companies’ products or reputation; risks related to adverse business conditions; our dependence on key employees; competition for qualified personnel; the possible unavailability of financing as and if needed; and risks related to protecting our intellectual property rights or potential infringement of the intellectual property rights of third parties. This list is intended to identify only certain of the principal factors that could cause actual results to differ from those discussed in the forward-looking statements. In light of these risks, uncertainties and assumptions, the events described in the forward-looking statements might not occur or might occur to a different extent or at a different time than we have described. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of the applicable presentation. You are referred to a discussion of important risk factors detailed in the Company’s Form 10-K filed with the Securities and Exchange Commission on March 8, 2018 and other reports and documents filed from time to time by us, which are available online at [www.sec.gov](http://www.sec.gov).

# CytoSorbents is a Leader in Critical Care Immunotherapy



Leading the Prevention or Treatment of  
**Life-Threatening Inflammation**  
in the ICU and Cardiac Surgery using  
CytoSorb® Blood Purification

# CytoSorbents At a Glance (NASDAQ: CTSO \$8)

- CytoSorb® is E.U. approved as an extracorporeal cytokine adsorber with 56,000+ cumulative treatments (up from 35,000 a year ago) delivered and distributed in 53 countries

- Record 2018 Financial Performance:

	2017	2018*	Increase
Total Revenue	\$15.1M	\$22.3M	+48%
Product Revenue	\$13.4M	\$20.2M	+51%
Blended Product Gross Margin	71%	>72%	-

- Healthy cash balance of \$22.3M (12/31/18)\*
- 120 employees with international footprint across two wholly-owned subsidiaries
  - CytoSorbents Medical, Inc: Headquarters - New Jersey, USA
  - CytoSorbents Europe GmbH: International sales office - Berlin, Germany
- Strategic Partnerships with Fresenius Medical Care, Terumo, Biocon, Dr. Reddy's
- Strong government support with ~\$26M in grants, contracts, other non-dilutive funds
- Russell 2000 & 3000 listed with coverage by Cowen, B Riley, HCW, Maxim, Zacks

# Uncontrolled Inflammation is Deadly



# Massive Inflammation Causes Organ Failure

Organ failure occurs when vital organs stop working,  
**causing nearly half of all deaths in the ICU.**



Little can be done to prevent or treat organ failure today

# No Ideal Options to Treat Severe Inflammation

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## **Anti-Inflammatory (too weak)**

**NSAIDs**

**Aspirin**

**Anti-cytokine  
antibodies**

**Anti-integrin  
antibodies**

**Anti-oxidants**

## **Immunosuppressive (too strong)**

**Corticosteroids**

**Chemotherapy**

**Organ transplant  
Anti-rejection drugs**

**Radiation**

**Immune system  
ablation**

**Anti-leukocyte Abs**

# CytoSorb® Reduces the Fuel to the Fire

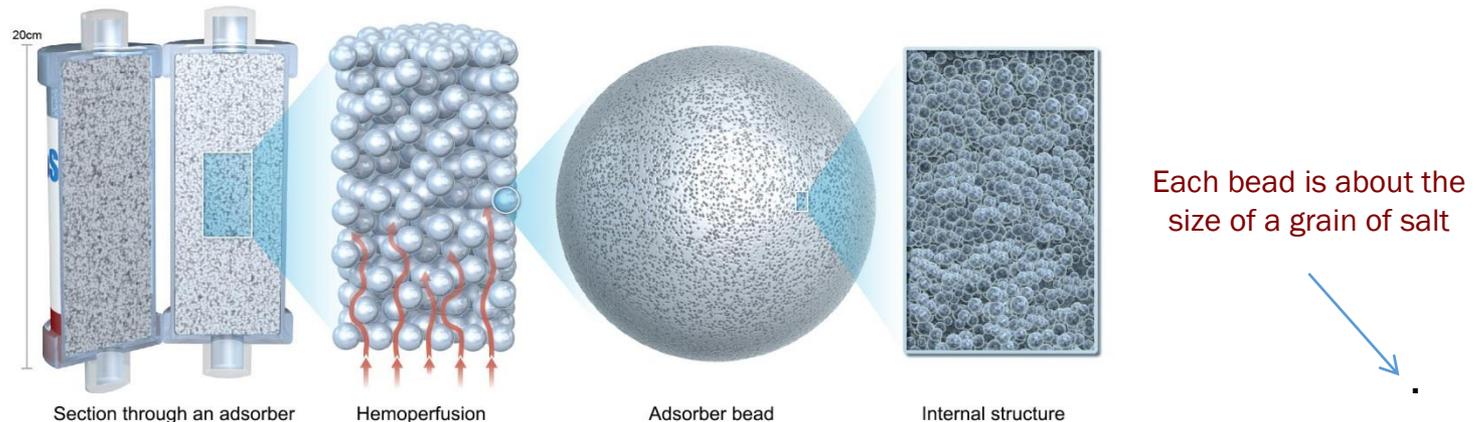
- CytoSorb® targets the \$20+ billion opportunity in critical care and cardiac surgery
- Approved in the European Union as the first specifically approved extracorporeal cytokine adsorber
- Broad indication for use where cytokines are elevated
- Removes cytokines and many other inflammatory mediators such as free hemoglobin, bacterial toxins, myoglobin, and activated complement
- Safe and well-tolerated: 56,000+ cumulative treatments delivered, up from 35,000 a year ago



\*CytoSorb is not yet approved in the U.S.

# Patented Blood Purification Technology

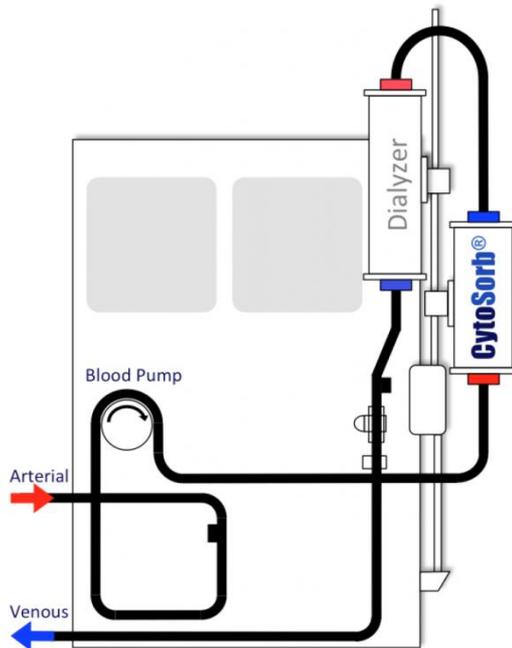
The underlying blood purification technology is based on biocompatible, highly porous polymer beads that act like tiny sponges to remove harmful substances from blood



- Proprietary patented technology with multiple patents pending worldwide
- Manufactured at our ISO 13485 certified facility in New Jersey
- One of the highest grade medical sorbents on medical market today

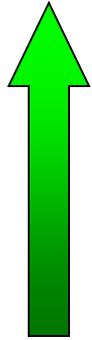
# CytoSorb is “Plug and Play”

## Compatible with Existing Dialysis and Heart-Lung Machines

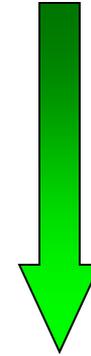


- Place a temporary dialysis catheter in a major vein
- Connect the device to a standard dialysis, ECMO, or heart-lung machine found in hospitals worldwide
- Pump blood out of the body and through the cartridge
- The polymer beads directly contact blood and remove unwanted or toxic substances
- “Purified” blood is pumped back into the patient
- Can treat 70+ total blood volumes per 24 hour treatment
- Each treatment uses a new cartridge

# Goal: To Prevent or Treat Organ Failure

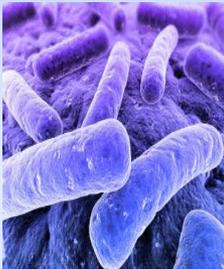


Improve  
Patient  
Outcome  
and  
Survival

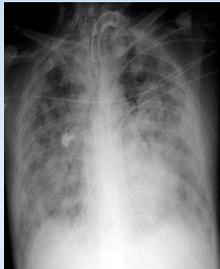


Decrease  
Costs Of  
ICU and  
Patient  
Care

Sepsis



ARDS



Burn Injury



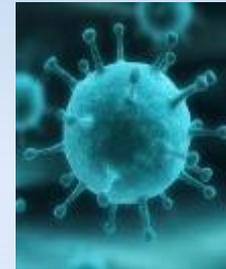
Trauma



Pancreatitis



Influenza



Surgical



The Potential to Revolutionize Critical Care Medicine

# Refractory Septic Shock

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Prospective, single arm study in 20 patients with refractory late-stage septic shock using CytoSorb aggressively every 12 hours with a new cartridge

- Patients had refractory shock despite high doses of vasopressors, respiratory failure requiring mechanical ventilation, oligo-anuric kidney failure requiring dialysis, and lactate > 8 mmol/L
- Results from the CytoSorb Greifswald Study
  - Resolution of shock in 65% of patients treated with CytoSorb
  - 28-day survival was 45%, a 30-40% absolute improvement over expected (0-10%)
  - Reduction of IL-6 from an initial average of 87,000 pg/mL to below 10,000 pg/mL after 24 hours of treatment
- A similar population (n=16) receiving standard of care but no CytoSorb therapy, where shock could not be reversed, also on mechanical ventilation with an initial lactate level of  $6.1 \pm 4$  mmol/L, and 75% requiring renal replacement therapy had a mortality of 100% at 28 days.\*
- Conrad, M., et. al., "Early prediction of norepinephrine dependency and refractory septic shock with a multimodal approach of vascular failure", J Crit Care, 2015; 30:739-743.
- Friesecke, S, et.al., "Extracorporeal cytokine elimination as rescue therapy in refractory septic shock: a prospective single center study", J Artif Organs 2017 Sep; 20(3):252-259.



# CytoSorb

56,000+ Treatments

53 Countries Worldwide with E.U.

Critical Care

Cardiac Surgery

United States

Cardiac Surgery



Many Investigator Initiated Studies



# CytoSorb® Is a High Margin “Razorblade”

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- High margin “razorblade” fully compatible with existing installed base of “razor” blood pumps: Dialysis/CRRT, ECMO machines (ICU), heart-lung machines (OR)
- Blended gross margins are >72%, expected to rise to ~80% on a quarterly basis in 2019, driven by volume production from our new manufacturing facility
- Average Direct Selling Price is approximately \$1,000 per cartridge
- Approximately 1 - 10 cartridges are typically used per patient
  - Open heart surgery: 1-2 cartridges
  - Sepsis: 3-5 cartridges or roughly 1 day in the ICU
  - Severe acute pancreatitis: 5-10 cartridges
- In Germany, 400 hospitals have >400 beds. Each hospital typically sees 300-600 sepsis patients per year. At 3-5 cartridges per patient:
  - Revenue per patient = ~\$3,000-5,000
  - Potential revenue per hospital = \$1-3M for sepsis alone
- Previously disclosed one German hospital has already achieved sales >\$1M, validating revenue model

# Direct Sales: Focused on 5 Countries



Dr. Christian Steiner, MD  
Vice President – Sales and  
Marketing and General Manager  
CytoSorbents Europe GmbH

CytoSorbents' direct sales force focused on most major university and public hospitals in Germany, Austria, Switzerland, Belgium and Luxembourg. German market alone is \$1.0-1.5 billion



# CytoSorb® Distributed in 53 Countries



Dr.Reddy's



HOANG LONG PHARMA

IntensivMed

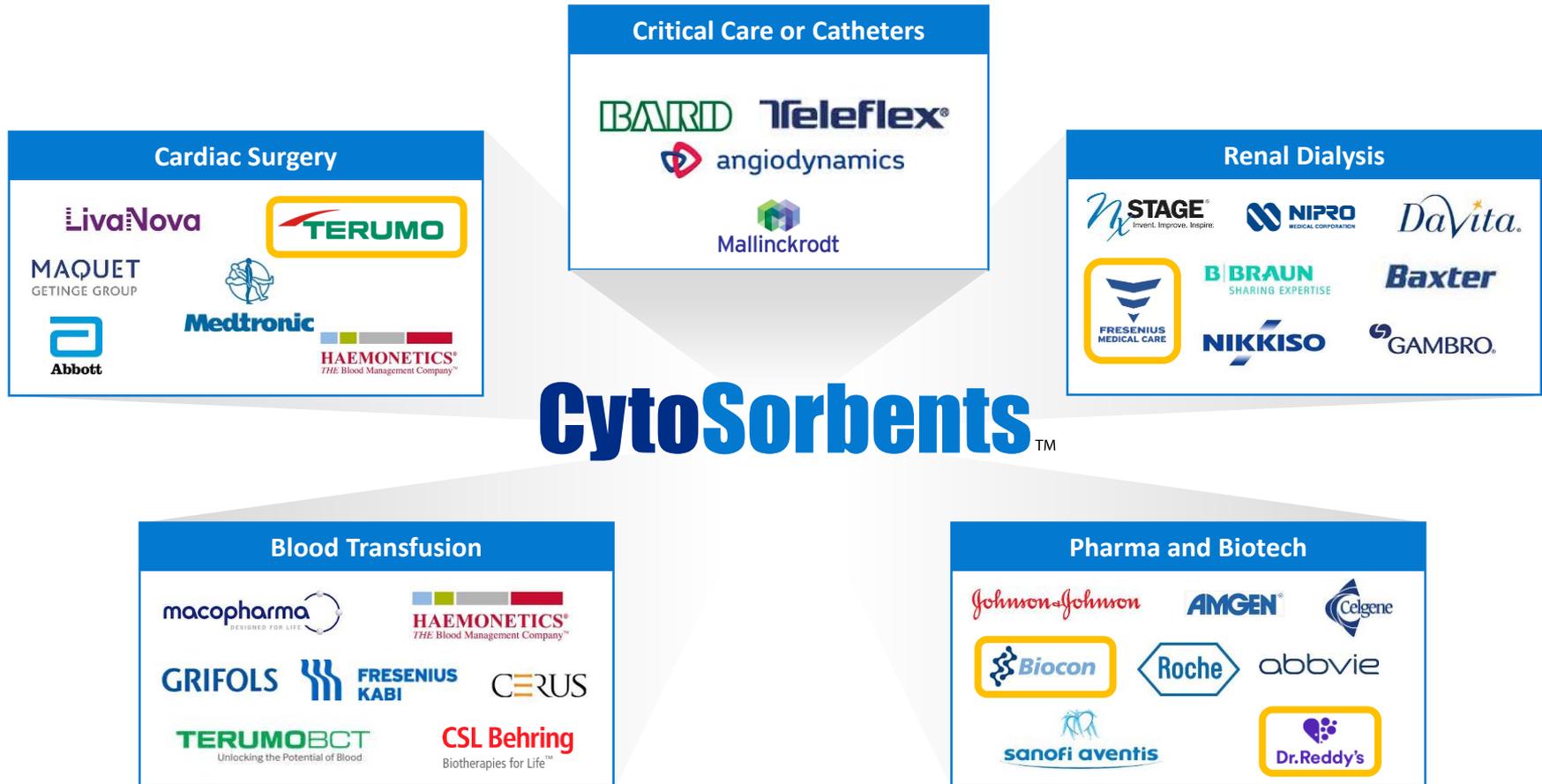


TekMed



WMC

# Four Major Partnerships, Potential for More



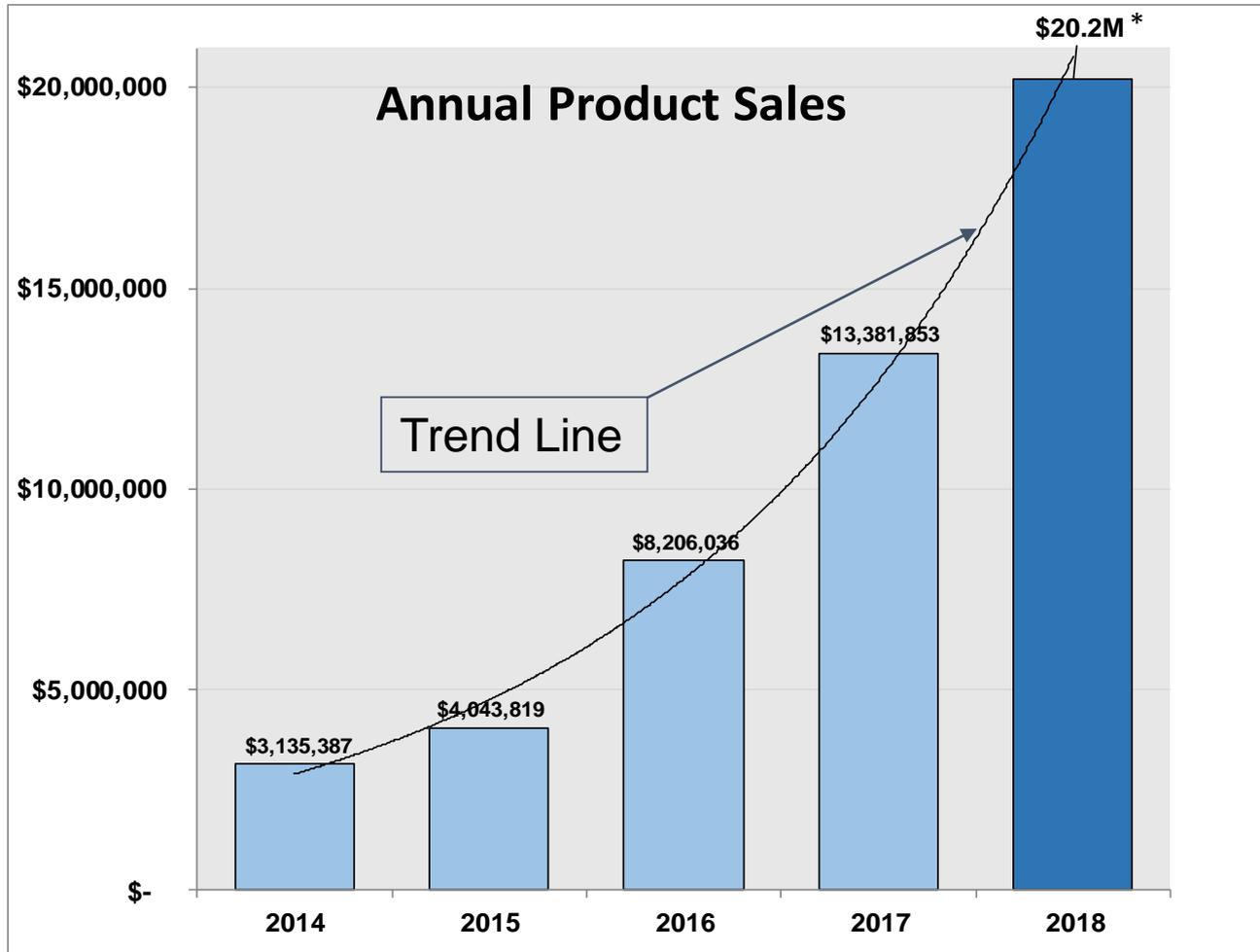
**Partnered with leading multinational corporations:**

**Fresenius Medical Care, Terumo Cardiovascular, Biocon Ltd, and Dr. Reddy's Laboratories**

\* Companies listed here are used simply as examples of companies in these respective verticals. We make no other representations as to our relationship with any of these companies.

# \$20M in Annual Product Sales

Twenty-six consecutive quarters of year-over-year product sales growth, with a three-year compound growth rate of return (“CAGR”) of 71%



\*Estimated

# REFRESH 2-AKI Pivotal Trial Targets U.S. Approval

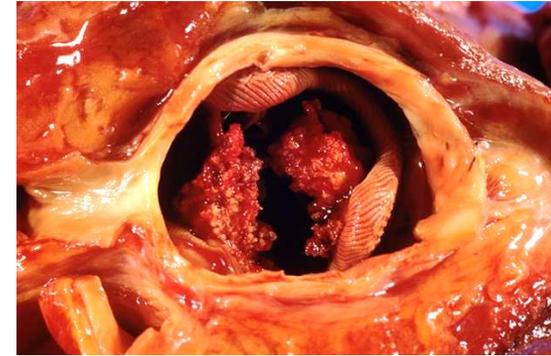
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- Heart disease is the leading killer worldwide, driving 1.5M open heart surgeries each year and fueled by the aging baby boomer generation
- High risk invasive cardiac surgery generates inflammatory toxins (e.g. free hemoglobin and activated complement) that can cause post-operative inflammation and organ injury such as acute kidney injury (AKI). CytoSorb reduces these toxins
- The development of even mild AKI after surgery predicts 1 and 5 year mortality and progression to chronic kidney disease
- REFRESH 2-AKI is a pivotal, multi-center RCT using CytoSorb intraoperatively to reduce the incidence or severity of AKI in high risk cardiac surgery
  - Up to 400 patient from 25 centers
  - Expected study completion: 2020 with potential 2021 FDA approval
  - Cost: Approximately \$12M spread out over 3 years
- Good progress in ramping the study, working with many excellent sites
  - 19 active sites, with four additional sites to be added soon – targeting 25 total trial sites
  - 39 patients enrolled by this week, up from 24 at the beginning of December. Targeting enrollment of 1 patient/site/month



# German Govt Funding REMOVE Endocarditis Trial

- Infective endocarditis (heart valve infection) occurs when bacteria seeds a heart valve from IV drug abuse and dirty needles, or from dental procedures
- The incidence of endocarditis is rising due to the opiate crisis
- Patients often require open heart surgery valve replacement but are very hemodynamically unstable before, during, and after surgery due to a combination of sepsis and heart valve destruction
- Intraoperative CytoSorb has been used to help stabilize such patients peri-operatively with good success
- The German Federal Ministry of Education and Research is funding a 250 patient, multi-center, randomized, controlled study (REMOVE) using CytoSorb during valve replacement open heart surgery in patients with infective endocarditis
- Primary endpoint is improvement of SOFA score
- Enrolled more than 60 patients to date. Interim analysis on reduction of inflammatory mediators planned on first 50 patients

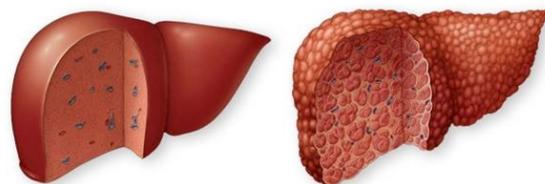


# Expanded Label Targets Liver Failure and Trauma

Recently received European approval to expand the use of CytoSorb in liver disease to reduce bilirubin, and in trauma to reduce myoglobin – both very large markets

- **Liver disease**

- 850 million people suffer from chronic liver disease due to viral hepatitis, alcoholism, and non-alcoholic fatty liver (NASH), and other causes leading to 1 million deaths from chronic liver disease, and another 1 million from hepatic cancer
- CytoSorb has been used as a liver dialysis therapy in numerous acute exacerbations of liver disease including acute-on-chronic liver failure, alcoholic hepatitis and others showing both bilirubin and bile acid reduction, and important clinical benefits such as hepatic coma reversal



- **Trauma**

- 56 million hospitalizations in trauma worldwide each year with approximately 5 million deaths. Severe crush injury of muscle releases myoglobin, called rhabdomyolysis, which can precipitate kidney failure, and increase the risk of death

# CAR-T Cell Immunotherapy and CRS

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- CAR-T cell cancer immunotherapy is a blood cancer treatment breakthrough.
- However, ~40-50% of patients can develop severe, high grade cytokine release syndrome (CRS), a cytokine storm that can lead to rapid organ failure and potentially death
- CytoSorb® was specifically designed to control cytokine storm and CRS and has already successfully treated a dozen cases of the closely related disease hemophagocytic lymphohistiocytosis (HLH)
- With FDA and E.U. approvals of Kymriah (Novartis) and Yescarta (Gilead), we are positioning CytoSorb® to be used as an alternative to, or in conjunction with, tocilizumab and steroids
- In 2017, the pioneer of CAR T-cell immunotherapy, Dr. Carl June at University of Pennsylvania, joined our Scientific Advisory Board



# Product Pipeline

Sepsis,  
Critical Care,  
High Risk  
Surgery



CE Mark Approved



U.S. Animal Health Market

## HemoDefend

Blood  
Transfusions



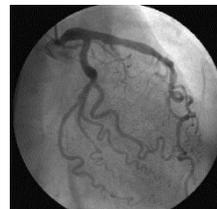
Nearing US Pivotal Trial

## CytoSorb-XL



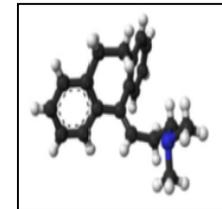
Sepsis,  
Critical Care,  
High Risk  
Surgery

## ContrastSorb



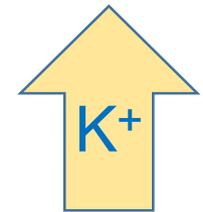
CT Imaging,  
Interventional  
Radiology

## DrugSorb



Drug Overdose,  
Chemo  
Removal

## K+ontrol



Severe  
Hyperkalemia

Under Development

# Near-Term Potential Catalysts

- Expected significant growth in sales and usage of CytoSorb, driven by:
  - Clinical data in more applications
  - Reimbursement in key territories
  - Investments in infrastructure and human capital to support our direct, distributor, and partner sales
- 2019 blended product gross margin expansion to 80% on a quarterly basis
- Potential new partnerships and expansion of existing partnerships
- Ramping of pivotal REFRESH 2-AKI and REMOVE studies
- Early 2019 start to HemoDefend pivotal US Trial
- Publications of clinical and research data
- Expanded institutional ownership and analyst coverage





***Providing Hope  
in a helpless situation***



HELPING PATIENTS SURVIVE CRITICAL ILLNESSES WORLDWIDE



**CytoSorbents™**

Working to Save Lives Through Blood Purification

NASDAQ: CTSO

Dr. Phillip Chan, MD, PhD – CEO

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